



Icahn  
School of  
Medicine at  
Mount  
Sinai

*Conduits*

The Institutes for Translational Sciences

[Sponsor Name], MD

[Title, Department]

Icahn School of Medicine at Mount Sinai

One Gustave L. Levy Place, Box [XXXX]

New York, NY 10029

[Date]

Food and Drug Administration

Center for Drug Evaluation and Research

Division of [Therapeutic Area]

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

### Request for Pre-IND Meeting

Dear Dr. [Division Director]:

In response to our conversation on [DATE], I am formally requesting a Type B meeting to discuss the proposed study [study title].

A proposed outline for discussion is provided below:

- **Product Name**
- **Chemical Name and Structure**
- **Proposed Indication(s)**
- **Type of Meeting Requested**  
Pre-IND, Type B meeting. We would prefer a teleconference as an alternative to a face-to-face meeting.
- **Statement of Purpose**  
To discuss [choose the possible following topics]
  - the intended product formulation
  - testing and data requirements
  - scientific issues that may need to be resolved
  - safety profile
  - chemistry
  - adequacy of manufacturing and control standards
  - clinical trial design
  - identification of potential clinical hold issues
- **Specific Objectives of Meeting**  
Obtain answers to submitted questions

- **Proposed Agenda**  
General Introductions  
Brief Review of Protocol  
Discussion of FDA Responses to Questions
- **Names of Participants from Name of Institution**
- **Proposed Date and Time for Teleconference**  
We would ask that the meeting be held Example: at any time other than Monday or Thursday mornings (PST) as the members of our research group have administrative responsibilities during those times. We propose the following dates in 201X:
- **The approximate date on which supporting documentation will be sent to the review division**  
Supporting documents will be submitted to FDA 30-days prior to the meeting date.

#### PRELIMINARY LIST OF QUESTIONS FOR FDA

**Regulatory:**

**Preclinical:**

**Chemistry, Manufacturing and Control:**

**Clinical Questions:**

If you require additional information, please contact me at the phone number or email address provided below.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address